

# **EXHIBIT M65**

PLAINTIFFS' EXHIBITS 000642

UDL LABORATORIES  
EXPIRATION DATING FORM

MACHINE: 230 RUN SIZE: 470,000

HOURS: 9.9 SPLIT LOT: Y N ✓

ACCOUNT FOR SAMPLES: Y ✓ N

MFG. DATE: 03/07 EXP. DATE: 03/09

LOT #: 2J525 PKG. CONFIG: UD100

8+ MTH REVIEW: N/A DATE: N/A

EXCEPTIONS: N/A JC 7/2/07

ASGN. EXP. DATE: 01/09 PKG. MATL: UVI

PC: WHS DATE: 7/02/07

REG: JC DATE: 7/2/07

UDL 1020R2      EFF. DATE: 4-13-99

EXHIBIT M65  
FOR ID: 126-10178

S-7157

RCV100-A

UDL Laboratories, Inc.  
Receiving FormDaily Log  
A4132-001

Date Received..... 6/21/07

Received From..... AMIDE/BERTEK/MYLAN

**CORRECTED  
COPY**

Shipped Via..... ABF

Receiving Lot No.... 7-06-261

Supplier Lot No.... 70175A1

Purchase Order No... 084105

Manufacture Date.... 03/07

Expiration Date..... 03/09

QUANTITY	ITEM No.	DESCRIPTION
96	30789	DIGITEK (DIGOXIN) 250 MCG (0.25 MG) TAB, USP BTL5000

Received By J. MylneDate 6-27-07UDL 910R1  
EFF. Date: 5-03-00

PLAINTIFFS' EXHIBITS 000644

Confidential Subject to Protective Order

UDLL 00000580E

RCV100-A

**UDL Laboratories, Inc.**  
**Receiving Form**

Daily Log  
A4132-001

Date Received..... 6/21/07

Received From..... AMIDE/BERTEK/MYLAN

Shipped Via..... ABF

Receiving Lot No... 7-06-261

Supplier Lot No.... 70175A1

Purchase Order No... 084105

Manufacture Date... NA

Expiration Date..... 03/09

QUANTITY	ITEM NO.	DESCRIPTION
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96 | 30789 | DIGITEK (DIGOXIN) 250 MCG  
| (0.25 MG) TAB, USP BTL5000

Received By J. M. C.

Date 6.21.01

UDL 910R1  
Eff. Date: 5-03-00

RCV110-B

UDL Laboratories, Inc.  
Receiving Inspection FormDaily Log  
A4132-001

Transaction Date.... 6/28/07 Receiving Lot No.... 7-06-261

Item Number..... 30789 Vendor Lot No..... 70175A1

## Product Description

DIGITEK (DIGOXIN) 250 MCG  
(0.25 MG) TAB, USP BTL5000VISUAL INSPECTIONSpecification No: S-7157  
Page Revision No: 006  
Code: ONE SIDE: B

Actual Count: 96

Case Qty:

8 CS @ 12 X 5000

Inspection Date: 6/28/07  
Caliper or Micrometer: #M5 & DM5  
Color: WHITEContainers Sampled: 3 BOTTLES  
Quantity Sampled: 80 TABS  
Defects Found: NONE 4-28-07  
4 tabs out of UDL's thickness  
toleranceSecond Sampling:  
Containers Sampled: NA  
Quantity Sampled: NA  
Defects Found: NANo of Skids 1  
Memo Attached: N YReduced Dating: 4-29-07  
NA

Sample: 20 QA SAMPLES

Inspection Results:  
Label Revision: RBK146Z1  
Insert Revision: 11/00  
Average Piece Weight: 0.120333  
Inspection Notes:  
NA

Tooling/Specification Sample: NA

Accept: X Reject: NA MRB No: NA

Reasons: NA

Q.A. Inspector: P. Finch Date: 6-28-07Verified by: D. McLean Date: 6-29-07UDL 945R5  
EFF: 02/28/03

ACTAVIS TOTOWA LLC

Fax: 19738907980

May 16 2007 14:36

P.18



101 E. Main Street, Little Falls, NJ 07424 • Ph: (973) 890-1440 • Fax: (973) 890-7980.

Digoxin Tablets, 0.25 mg      BATCH # 70175A

CERTIFICATE OF ANALYSIS GENERATED FOR  
CUSTOMER PURPOSES ONLY

All testing has been performed in accordance with GMP and GLP and all results have been found to comply with the registered specifications.

Part of Bulk Batch # 70175A is bottled as Control # 70175A1  
(PACK SIZE 5000)

Manufactured Date: 03/02/2007

Approved By: L. L (S) Date: 3/27/07  
Regulatory Affairs

pt  
6.27.07

Actavis Totowa LLC

## CERTIFICATE OF ANALYSIS

Product Name: Digoxin Tablets, 0.25 mg

Date of Analysis: 03/27/07 Control No: 70175A Exp. Date: March 2009

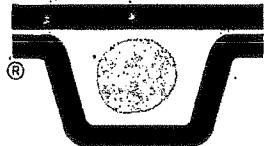
DESCRIPTION:	TEST	RESULTS	REPORT
DESCRIPTION: Color:	White	White	
Profile:	Round bisected tablets	Round bisected tablets	
Other: Debossed	"B" 146" on bisected side	"B" 146" on bisected side	
STABILITY:	0.1%	NMT 1.0%	
IDENTIFICATION: (A)	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.	
(B)	The Rf value of test solution corresponds to standard solution.	The Rf value of test solution corresponds to standard solution.	
ASSAY:			
Digoxin, 0.25 mg	98.8%	90.0% - 105.0%	
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity)	1) 98.0% 2) 96.2% 3) 100.0% 4) 97.6% 5) 98.1%	6) 98.7% 7) 95.8% 8) 98.8% 9) 97.7% 10) 99.1%	85.0% - 115.0% RSD: NMT 6.0%
Digoxin, 0.25 mg	Average: 98.0%	SD: 1.26%	
DISSOLUTION:	1) 98.0% 2) 101.6% 3) 95.6%	4) 97.0% 5) 98.7% 6) 101.4%	NLT 80 % (Q) of the labeled amount of Digoxin is dissolved in 60 minutes.
Media: 500mL; 0.1N HCl Apparatus: I, RPM: 120 Temp: 37.0°C ± 0.5°C Time: 60 minutes	Average: 98.7%		
Related Substances:			
Digoxigenin	0.625%		NMT 2.0%
Digoxigenin bisdигитоксозид	0.493%		NMT 2.0%
Gitoxin	Not detected		NMT 3.0%

for *CDP*  
Director of Quality Control*03/27/07*  
Date*PT  
6.27.07*

**PURCHASE ORDER**

## EQUAL EMPLOYMENT OPPORTUNITY POLICY

It is the policy of UDL Laboratories, Inc. to give fair consideration to all qualified persons, and all employees opportunities for advancement according to their individual abilities regardless of race, religion, color, national origin, sex, marital status, sexual preference, age, handicap, or veteran status. No opportunity for promotion, transfer, compensation or any other benefit of employment will be diminished through discriminatory practices. In addition, UDL agrees to take affirmative action to ensure equal employment opportunity.

**UDL LABORATORIES, INC.**

1718 Northrock Court  
Rockford, IL 61103-1201  
(815) 282-1201

**PURCHASE ORDER NO.** 64105  
**DATE ISSUED** 6/23/07

3434-10  
**ORDER TO:** AMIDES/PERTEK/MYLAN  
 781 CHESTNUT RIDGE RD.  
 P.O. BOX 4310  
 MORGANTOWN WV 25504-4310  
**SHIP VIA:** CONNIE HATCHER  
 REST DAY

**SHIP TO:** UDL DISTRIBUTION  
 4951 HIAWATHA DR  
 ROCKFORD IL 61103-1207

RUDOLPH A. HATCHER  
 PAYMENT TERMS: P

AH132  
*Reinhart*

ITEM	DESCRIPTION	QTY. ORDERED	QTY. REC'D.	PRICE	AMOUNT
30789 146-56	DIGITEK (DIGOXIN) 250 MCG (0.25 MG) TAB, USP PTL5000	95.00	96	59.770 00	5737.92
7-06-261	DUE DATE: 6/14/07 70175A1 3/09 3/07 LABEL: PERTEK		96	6-28-07	
	CONFIRMING PER:				
	CONFIRMING ORDER: PRODUCT SHIPPED MUST HAVE 18 MONTHS DATING. CERTIFICATE OF ANALYSIS MUST ACCOMPANY ORDER. SHIP ALL SAME LOT.				
	NOTE: IF PRODUCT TO BE SHIPPED ON THIS ORDER HAS BEEN REFORMULATED, CONTACT UDL BEFORE SHIPPING.				

**SHIP VIA** ABF

**ORDER TOTAL**

5737.92

REC'D. BY MIA DATE \_\_\_\_\_

Q.C. INSPECTOR P. Finch ACC. / REJ. \_\_\_\_\_ DATE 6-28-07

3

# Mylan Pharmaceuticals Inc.



Sold By:  
 Name: Mylan Pharmaceuticals Inc.  
 Street: 781 Chestnut Ridge Road  
 City: Morgantown  
 State: WV Zip: 26504-4310

Federal ID Number: [REDACTED]

Telephone Number: 304-599-2595

Sold To:  
 Name: UDL Laboratories, Inc.  
 Street: 1718 Northrock Court  
 City: Rockford  
 State: IL Zip: 61103

Material	Product Description	Batch Number	Qty Ordered	Qty Shipped	Qty B.O.	Complete Cartons	Repack Cartons	Repack Quantity
Pallet 62794-146-56	100303780000587145 Digitek 0.25 mg 5000s	70175A1	96	96	0	8 X 12		

Page 1 of 1



80020813

Shipped From:	Name: Mylan Pharmaceuticals Inc. Distribution Center Street: 2898 Manufacturers Road City: Greensboro State: NC Zip: 27406 DEA Number: RM0130093 DC Phone Number: 1-800-446-9526
Shipped To:	Name: UDL Laboratories, Inc./Rockford, IL Street: 4951 Hiawatha Drive City: Rockford State: IL Zip: 61103-1287

Material	Product Description	Batch Number	Qty Ordered	Qty Shipped	Qty B.O.	Complete Cartons	Repack Cartons	Repack Quantity
Pallet 62794-146-56	100303780000587145 Digitek 0.25 mg 5000s	70175A1	96	96	0	8 X 12		

(8 Ctns x 12) = 96  
 Lot 70175A1  
 Exp 03 09  
 J:m:6  
 6 - 21.07  
 A B F

# Ctns Complete: 8  
 # Repack Ctns:  
 Total: 8  
 Filled By: DKPHILLI



ABF FREIGHT SYSTEM, INC.				CORR = A	
(ABFS) CONSIGNEE COPY				PAGE 3 OF 3	
⑥ TERMINAL 815-874-6866		DUN'S 00-690-2977 06/21/07 03:09		FREIGHT BILL NO 051103126	
SHIPPER NO. 3223 PICK UP DATE 06/19/07 SHIPPER 1150 SEE BELOW		CODE TO PONO. NO OF POS = 082097-0020		ROUTING 1.2 CONSIGNEE 082097-0014	
MYLAN PHARMACEUTICALS 2698 MANUFACTURERS RD GREENSBORO NC 27406		DESCRIPTION		WNS-RFD UDL LABORATORIES INC 4951 HIGHLAND DRIVE ROCKFORD IL 61103	
PIECES		DESCRIPTION		WEIGHT (LBS)	RATE CHARGES
		POIS 84256	96 WEIGHT	706 LB	
		PCS 84259	5 WEIGHT	10 LB	
		POIS 84260	3 WEIGHT	10 LB	
		PCS 84261	42 WEIGHT	662 LB	
		POIS 84262	13 WEIGHT	10 LB	
		POIS 84278	6 WEIGHT	10 LB	
		PCS MEASURED CUBE: 224,000 CUFT			
		ABF			
		THANKS FOR SHIPPING ABF			
		BILL TO		2,855 PREPAID PAY THIS AMOUNT	
		RE		PB ABF 610 TAR ABF 610 OZP 27406 DZP 61103 SPEC HAND	
		CUST HELP UNLDP Y... N...		CONSIGNEE	
CUBE 0.224 DELIVERY DUE 06/21 DELIVERY DATE 06/21 DRIVER		PRIORITY DATE		J. m. l. 6.21.07	
BY (CUSTOMER'S SIGNATURE)					

**PLAINTIFFS' EXHIBITS 000652**

Confidential Subject to Protective Order

UDLL 000005814

UDL LABORATORIES, INC.  
PRODUCT INSPECTION RECORDPage 1 of 1Product Description Digitek (digoxin tablet, usp) 250 mcg (0.25 mg)Manufacturer/Supplier Amidex/BertekManufacturer Lot # 70175A1 Receiving Lot # 7-06-2601

DIAMETER	THICKNESS	LENGTH	WIDTH
1. <u>7.19</u> mm	1. <u>3.15</u> mm	1. _____ mm	1. _____ mm
2. <u>7.21</u> mm	2. <u>3.16</u> mm	2. _____ mm	2. _____ mm
3. <u>7.20</u> mm	3. <u>3.14</u> mm	3. _____ mm	3. _____ mm
4. <u>7.21</u> mm	4. <u>3.16</u> mm	4. _____ mm	4. _____ mm
5. <u>7.20</u> mm	5. <u>3.17</u> mm	5. _____ mm	5. _____ mm
6. <u>7.21</u> mm	6. <u>3.17</u> mm	6. _____ mm	6. _____ mm
7. <u>7.20</u> mm	7. <u>3.14</u> mm	7. _____ mm	7. _____ mm
8. <u>7.21</u> mm	8. <u>3.12</u> mm	8. _____ mm	8. _____ mm
9. <u>7.21</u> mm	9. <u>3.19</u> mm	9. _____ mm	9. _____ mm
10. <u>7.20</u> mm	10. <u>3.18</u> mm	10. _____ mm	10. _____ mm
11. <u>7.20</u> mm <small>+ 6-28-07</small>	11. <u>3.14</u> mm	11. _____ mm	11. _____ mm
12. <u>7.21</u> mm	12. <u>3.17</u> mm	12. _____ mm	12. _____ mm
13. <u>7.20</u> mm	13. <u>3.18</u> mm	13. _____ mm	13. _____ mm
14. <u>7.20</u> mm	14. <u>3.17</u> mm	14. _____ mm	14. _____ mm
15. <u>7.21</u> mm	15. <u>3.18</u> mm	15. _____ mm	15. _____ mm
16. <u>7.21</u> mm	16. <u>3.18</u> mm	16. _____ mm	16. _____ mm
17. <u>7.23</u> mm	17. <u>3.17</u> mm	17. _____ mm	17. _____ mm
18. <u>7.20</u> mm	18. <u>3.20</u> mm	18. _____ mm	18. _____ mm
19. <u>7.21</u> mm	19. <u>3.16</u> mm	19. _____ mm	19. _____ mm
20. <u>7.21</u> mm	20. <u>3.18</u> mm	20. _____ mm	20. _____ mm
Average <u>7.21</u> mm	<u>3.17</u> mm	_____ mm	_____ mm
Range <u>7.19-7.23</u> mm	<u>3.12-3.20</u> mm	_____ mm	_____ mm

INSPECTOR P. Finch DATE 7-28-07UDL 940R2  
Eff. Date: 6-7-00  
(Orig. 2-16-98)

UDL LABORATORIES, INC.

MEMORANDUM

To: The Receiving Report

From: Eva Cantu *EC*

Date: August 15, 2006

Re: *Documentation of Supplier Name Change – Amide/Bertek/Mylan*

The products that were supplied by Bertek and manufactured by Amide; are now being supplied by Mylan. However, the product label and insert still reflect Amide/Bertek. Until the supplier's product label and insert reflect a name change, UDL will continue to record Amide/Bertek on its product specification and labeling.

This memorandum will be placed in the batch record to explain the inconsistency of the supplier/manufacturer name on the paperwork/documents within the batch record.

cc: Vince Mancinelli, Sue Powers, Li Radtke, Mike Armstrong, Shirley Svejcar, Val Schissel, Yvette Smith, Paul Trost, Phyllis Fender

**UDL LABORATORIES, INC.**  
**MEMORANDUM**

**TO:** The File  
**FROM:** Peggy Finch  
**DATE:** December 11, 2006  
**RE:** Documentation of Amide Pharmaceuticals and Actavis

As of December 20, 2005, Actavis acquired Amide Pharmaceuticals. Amide has begun adding Actavis to its documents; however, its product label and insert still record Amide. During this transition period, some UDL documents within the batch record will reflect Amide and/or Actavis. Once the name change is reflected on the product label and insert, UDL will update its labeling and documents.

This memo will explain the inconsistency of Amide and/or Actavis observed on the documents.

A copy of this memo will be attached to the affected receiving reports.

**cc:** Sue Powers  
Eva Cantu  
Li Radtke  
Shirley Svejcar  
Val Schissel  
Teresa Wilmot

UDL LABS



TARE WT: 1.13 GRAMS



APW: 0.120333 GRAMS



QTY: 20

TIME: 9:46 AM

DATE: 28 JUN 2007